NATIONAL INSTITUTES OF HEALTH NIH Ethics Program

Procedure for Completing and Reviewing the HHS-521, Annual Report of Outside Activity

Due Date: The report is due on February 28th.

Extension: An extension may be requested from your Deputy Ethics Counselor for good cause.

Request the extension in writing before the due date; include your justification (Request

via email is acceptable).

Submit to: Your Supervisor, who must receive it by close of business on the due date.

Reporting Period: Previous calendar year.

What to Report: Report all Outside Activities which occurred at any time during the prior calendar

year, including those which began in a previous year and continued through any portion of the reporting period, and those which began during the reporting period

and continued into the present calendar year.

Help: For assistance, contact your IC's Ethics Office. Names and addresses of Ethics

Coordinators are available on the NIH Ethics Program web site.

EMPLOYEE: GETTING STARTED

1. Gather the information about all of the Outside Activities and other outside employment which must be reported. See the "Outside Activity Information" section, below.

2. Obtain the form HHS-521 from the NIH Ethics Program web site, on the Ethics Forms page: http://ethics.od.nih.gov/forms.htm (Scroll down to the HHS-521 form.)

The form is in fillable format. If you have Acrobat Reader version 6 or higher, you may be able to complete the form and save it. Click on the form link, choose "Save" and save the file in a directory or on a disk so you can find it.

- 3. Open the form, press the "Tab" key, and complete the form as follows.
- 4. Insert the last two digits of the calendar year. (Insert one digit, tab to the second space.)
- 5. If you were granted an extension, enter the Extension Date in the space provided.
- 6. Date Report Filed will be completed by the Supervisor.

PART I. EMPLOYEE INFORMATION (Page 1)

When using the fillable format form, enter the requested information and tab to the next field.

- 1. Name: self explanatory
- 2. Agency (op/Staff Div) NIH

Agency (Component) Enter your IC's acronym, e.g., OD, NIA, NCI, etc.

- 3. Enter your official NIH/IC title.
- 4. Enter your Grade and Step if you are GS or WG. If you are in a non-graded pay system, enter N/A.
- 5. Enter your annual federal salary amount (total compensation benefit).
- 6. Check the relevant box to indicate your appointment type:
 - PAS/PA: Presidential Appointee Senate Confirmed / Presidential Appointee
 - Non-Career SES
 - Schedule C
 - Commissioned Corps
 - Career SES: applies to SES appointees at the NIH
 - GS: General Schedule: GS and WG employees
 - Other: indicate the appointment type if none of the above fit, e.g., Title 42
- 7. Financial Disclosure Filing Status: indicate which form you file, or None if you do not file a financial disclosure report.
- 8. Office Address: self-explanatory, give complete information as requested.
- 9. Office Contact Information: self-explanatory, give complete information to contact you.
- 10. Name of Immediate Supervisor: self-explanatory.
- 11. Title of Supervisor: self-explanatory.
- 12. Supervisor Contact Information: self-explanatory, give complete information to contact your supervisor.

PART II. OUTSIDE ACTIVITY INFORMATION (Pages 2-3)

Report all Outside Activities approved via the HHS-520 which took place during any portion of the calendar year covered by the report, regardless of when the activity started or ended. Also report any activities you engaged in during the calendar year covered by the report for which should have received advance approval. Report activities which may have been approved in a previous year but which occurred at any time during the calendar year covered by the report.

Note that each line is designated with a letter. In questions 1 through 4, add information about each activity such that the information in all of the Line A's refers to the same activity detailed in Question1 Line A, all Line B information is about the same activity, etc. If you do not need all the lines, when you finish entering all the information in numbers 1, 2, 3, and 4, use your mouse to move the cursor to question number 5. You may also tab through all the blanks for each lettered line.

1. Outside Activity List: Carefully read the instructions and complete the information requested.

If you had no Outside Activities to report, check the "None" box. You do not need to continue the report.

- Outside Activity means the type of activity, e.g., teaching, consulting, professional practice, testimony, etc.
- Person or Organization means the name of the entity for which you work in your Outside
 Activity. Normally, you work for an organization and the person is your contact with that
 organization.
- <u>Approval Date</u> means the date of the latest approval to engage in the Outside Activity, e.g., the date the request was signed by your approving authority, usually your Deputy Ethics Counselor.
- Add a checkmark (✓) to indicate whether you actually engaged in the activity. If you received permission but did not actually conduct the activity, leave this block blank.
- **2. Duration:** self-explanatory. Enter the dates and times as requested.
 - <u>Beginning Date</u> means the approved start date, either the date you requested to start the activity, or, if the activity was approved after the requested start date, then the date you were actually permitted to begin, i.e., the same as the approval date.
 - <u>Service Date(s)</u> means the dates or time frame during which you actually engaged in the activity, e.g., the date you began through the date you stopped, even if it the same as the Beginning Date above.
 - Hours Spent means total number of hours you worked on the activity, including preparation, travel, and participation times.
 - <u>Leave Used</u> means total number of hours of annual leave or leave without pay you used to work on the activity.
 - <u>Ending Date</u> means the date you completed, or expect to complete, the work associated with the activity.
 - <u>Renewal Anticipated?</u> requests that you indicate whether you expect to request renewal of the activity at the appropriate time. Check the box appropriate for each activity.
- 3. Income and/or Reimbursements Paid. Read the instructions carefully. Report travel expenses reimbursed or provided in kind separate from payment, e.g., honorarium, fee, etc. The columns are self-explanatory.
- **4. Income and/or Reimbursements Due**. Read the instructions carefully. Report only those travel expenses, reimbursements, and/or payments you expect to receive but have not yet received. Note that the first column has a typographical error in the column heading; it should read Payment Expected.
- **5. Employee Questions.** Carefully read and respond to each question. Note that some responses require you to add text. If there is insufficient space below the "No" option, use the Additional Space on page 10, and identify the question number to which the text in the Additional Space applies.
- **6. Certification.** Carefully read the certification and sign and date to indicate that you have read the statement and reported everything accurately.

Make a copy for yourself and provide the completed original form HHS-521 to your supervisor no later than close of business on February 28th each year.

SUMMARY OF WHERE REVIEWERS SIGN (Pages 4-6)

The HHS-521 contains three sections where reviews are documented. For consistency across the NIH, the following table provides instructions for use of the various signature blocks. Submissions which meet the criteria in the first 3 columns (e.g., whether the IC require second level supervisory review, or if the activity falls under the jurisdiction of the NIH Ethics Advisory Committee) will use the signature sections as indicated.

Since the HHS-521 may include activities which fall under different jurisdictions, if any activities fall under NEAC, then both the IC and NEAC signatories will sign where indicated, and add the line identification for each activity being reviewed.

When a report contains activities for both IC DEC and NEAC/NIH DEC review, each will sign in the section indicated below, and in the Comments section, indicate which activities are covered by the signature, using the line identification letter from page 2 (and additional space if more than 6 activities are reported).

Conditions			Section III Supervisor Review	Section IV Management /	Section V Agency Ethics
Who Submits	2 nd Level Review	NEAC		Committee / Other Review	Official Review
IC Staff	N	N	Supervisor	Leave Blank	DEC or Ethics Coordinator*
IC Staff	Υ	N	Supervisor and 2 nd level reviewer	Leave Blank	DEC or Ethics Coordinator*
IC Staff	N	Υ	Supervisor	IC DEC	NEO
IC Staff	Y	Y	Supervisor and 2 nd level reviewer	IC DEC	NEO
Top 5** (other than IC Directors)		Υ	Supervisor	IC DEC	NEO
IC Directors		Υ	Leave Blank	IC DEC	NEO

^{*} If authority has been delegated by the DEC.

PART III. SUPERVISOR REVIEW (Page 4)

- 1. **Date Received:** Enter the date you received the form in the "Date Report Filed" block near the top right of page 1.
- 2. Read the Summary of Applicable Law on page 4. Contact your IC's Deputy Ethics Counselor or Ethics Coordinator if you have questions. Names are available on the NIH Ethics Program web site at: http://ethics.od.nih.gov
- **3. Review** the report and any additional information. Carefully read the instructions, review the report and any additional information. Your review includes confirming that the employee has an approved HHS-520 for each activity listed, and that you still agree that the Outside Activity is appropriate.

If you are unsure whether the employee has approved HHS-520, Request for Approval of Outside Activity, in place for each activity which requires advance approval, ask the employee to provide a copy or contact your Ethics Coordinator (http://ethics.od.nih.gov/coord.htm). Also, confirm that the

^{** &}quot;Top 5" based on the NIH definition

employee is recused from any official matters involving the specific parties with which the employee has a personal or Outside Activity. See table below for guidance for where to sign.

- **4. Sign and Date:** Sign where indicated, and add the date you sign. Your signature indicates that you have accomplished the review per the instructions on the form and this document.
- **5. Comments:** Add other comments as needed in block 3.

PART IV. MANAGEMENT/COMMITTEE/OTHER INTERMEDIATE REVIEW (Page 5)

For use as indicated in above Summary of Where Reviewers Sign, above.

- 1. Name of Reviewer: self-explanatory.
- 2. Title of Reviewer: self-explanatory.
- 3. Reviewer Contact Information: Self-explanatory. Provide all information requested.
- **4. Organization:** Insert the Reviewer's organization, if different than the employee's, e.g., Reviewer's Title may be Division Director, and Organization is the name of the Division.
- **5. Committee**: If the review is accomplished by an individual rather than a committee, insert N/A. Otherwise, insert the full name of the committee charged with second level review.
- 6. Review and Sign: Read the instructions, check the appropriate box, and sign and date. Confirm approved requests are in place for those activities which require advance approval, and that the employee is recused from any official matters involving the outside entities with which the employee has a personal or Outside Activity. Your signature confirms that you have complied with the instructions on the form and this document, and you agree that the activities are still appropriate as Outside Activities.

Note: For reports containing activities under the jurisdiction of the IC DEC, this page is left blank. For other activities under the jurisdiction of the NIH DEC, the IC DEC (or designee) will sign in this section, and in the comments section indicate the letter identification of each line (activity) being approved.

7. **Comments**: Insert any additional comments in this block.

PART V. AGENCY ETHICS OFFICIAL REVIEW (Page 6)

For use as indicated in above Summary of Where Reviewers Sign, above.

Note: See NIH Ethics Manual, chapter 2400-09, for policy regarding delegation of authority for final review and signature on page 6 of the HHS-521. A Deputy Ethics Counselor may delegate authority to the Ethics Coordinator to conduct final review and signature, if such a position exists in the specific Institute or Center (IC). Such delegation must be in writing and a copy forwarded to the NIH Ethics Office.

1. Name of Reviewer: self-explanatory.

- 2. Title of Reviewer: self-explanatory.
- 3. Reviewer Contact Information: self-explanatory.
- 4. Organization: Enter the organizational location/office designation of the Deputy Ethics Counselor responsible for making decisions for this individual. For example, activities and individuals under the jurisdiction of the NIH DEC or NEAC, the Ethics Official with be the NIH DEC.
- 5. Committee: Read the instructions and add the requested information, if applicable.
- 6. Ethics Review: Read the instructions carefully, review the form HHS-521, and mark the appropriate box to indicate concurrent or non-concurrence with the supervisor and second level review. Check the files or electronic tracking system to confirm that an approved HHS-520, Request for Approval of Outside Activity, exists for each reported activity which requires such approval. See the NIH Ethics Manual, Chapter 2400-09, Outside Activities, for guidance on which activities need advance approval, based on the relevant regulation. Sign and date the form. For reports containing activities only under the IC DEC's jurisdiction, the IC DEC signs on this page. For reports containing activities both under the jurisdiction of the IC DEC and other activities under the jurisdiction of the NIH DEC, the IC DEC (or designee) will have signed in the previous section and the NIH DEC signs on this page.
- 7. **Comments:** Insert any additional comments in this block. In this section, the NIH DEC (or designee) will indicate the letter identification of each line (activity) being approved.

ETHICS STAFF FINALIZE THE REPORT

This section applies to the Ethics Office where the final ethics review occurs. Reports on activities under the jurisdiction of the NIH DEC are handled in the NIH Ethics Office; others are handled within the IC Ethics Offices.

- 1. Make a copy of the full report for the employee. Return it to the employee with a route slip through the second level reviewer and the supervisor. Inform the employee of any issues that need to be resolved, e.g., an activity which had any significant changes for which you require a resubmitted request package.
- 2. Enter the appropriate data in EMIS. Locate the employee in the NIH Ethics Management Information System (EMIS). Choose HHS-520s to see the list of Outside Activities, and click on "Edit" next to the record on which the employee is reporting. Scroll to the bottom to the HHS-521 heading and click on "Add New". Enter the information for each Outside Activity reported on the HHS-521 per the EMIS instructions.
- 3. File the original report in the employee's ethics file.

NIH Ethics Office; FP/TM; 521-Procedure.wpd